Thimerosal-Containing Influenza Vaccine

Q & A

1. What is thimerosal?

Thimerosal is a very effective preservative that has been used since the 1930s to prevent contamination in some multi-dose vials of vaccines (preservatives are not required for vaccines in single dose vials). Thimerosal contains approximately 49% ethylmercury. There is no convincing evidence of harm caused by the low doses of thimerosal in vaccines, except for minor reactions like redness and swelling at the injection site. However, in July 1999 the Public Health Service (PHS) agencies, the American Academy of Pediatrics (AAP), and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure.

Today, all routinely recommended licensed pediatric vaccines that are currently being manufactured for the U.S. market contain no thimerosal or only trace amounts. Please click on thimerosal to find more information on this site on thimerosal.

2. Does the influenza vaccine contain thimerosal?

Yes, the majority of influenza vaccines distributed in the United States currently contain thimerosal as a preservative. However, some contain only trace amounts of thimerosal and are considered by the Food and Drug Administration (FDA) to be preservative-free. Manufacturers of preservative-free flu vaccine use thimerosal early in the manufacturing process. The thimerosal gets diluted as the vaccine goes through the steps in processing. By the end of the manufacturing process there is not enough thimerosal left in the vaccine to act as a preservative and the vaccine is labeled 'preservative-free'.

3. Can I get an influenza vaccine that does not contain thimerosal?

For the 2002-2003 flu season, a limited number of individually packaged doses of preservative free, reduced thimerosal-content influenza vaccine are available from Evans Vaccines and Aventis Pasteur. The Evans reduced thimerosal-content vaccine is approved for use in persons over the age of 3 years. In September 2002, the FDA approved Aventis Pasteur's Fluzone® Preservative-free: Pediatric Dose, Influenza Virus Vaccine for use in children 6 months of age and older. Fluzone® is packaged in 0.25 ml dose syringes for persons under 3 years of age, and in 0.50 ml dose syringes for persons 3 years and older (including pregnant women).

4. Is it safe for children to receive an influenza vaccine that contains thimerosal?

Yes. There is no convincing evidence of harm caused by the small doses of thimerosal in vaccines, except for minor effects like swelling and redness at the injection site due to sensitivity to thimerosal. Most importantly, since 1999, newly formulated thimerosal preservative-free childhood vaccines (Hepatitis B, Hib, and DTaP) have been licensed. With the newly formulated childhood vaccines, the maximum total exposure during the

first six months of life will now be less than three micrograms of mercury. Based on guidelines established by the FDA, the Environmental Protection Agency (EPA) and the Agency for Toxic Substances and Disease Registry (ATSDR), no child will receive excessive mercury from childhood vaccines regardless of whether or not their flu shot contains thimerosal as a preservative.

Recent research suggests that healthy children under the age of 2 are more likely than older children and as likely as people over the age of 65 to be hospitalized with flu complications. Therefore, vaccination with reduced or standard thimerosal content flu vaccine is encouraged when feasible in children, including those that are 6-23 months of age.

5. Is it safe for pregnant women to receive an influenza vaccine that contains thimerosal?

Yes. A study of influenza vaccination examining over 2,000 pregnant women demonstrated no adverse fetal effects associated with influenza vaccine. Case reports and limited studies indicate that pregnancy can increase the risk for serious medical complications of influenza. One study found that out of every 10,000 women in their third trimester of pregnancy during an average flu season, 25 will be hospitalized for flu related complications.

Additionally, influenza-associated excess deaths among pregnant women have been documented during influenza pandemics. Because pregnant women are at increased risk for influenza-related complications and because a substantial safety margin has been incorporated into the health guidance values for organic mercury exposure, the benefits of influenza vaccine with reduced or standard thimerosal content outweighs the theoretical risk, if any, of thimerosal.

References

Ball LK, Ball R, Pratt RD. An assessment of thimerosal use in childhood vaccines. Pediatrics 2001;107(5):1147-54.

Centers for Disease Control and Prevention. Prevention and control of influenza; recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2002; 51(RR03):1-31.

Centers for Disease Control and Prevention. Recommendations regarding the use of vaccines that contain thimerosal as a preservative. MMWR 1999;48(43):996-8.

Heinonen OP, Shapiro S, Monson RR, Hartz SC, Rosenberg L, Slone D. Immunization during pregnancy against poliomyelitis and influenza in relation to childhood malignancy. Int J Epidemiol 1973;2:229--35.

Izurieta HS, Thompson WW, Kramarz P, et al. Influenza and the rates of hospitalization for respiratory disease among infants and young children. New Engl J Med 2000;342:232--9.

Kirshon B, Faro S, Zurawin RK, Samo TC, Carpenter RJ. Favorable outcome after treatment with amantadine and ribavirin in a pregnancy complicated by influenza pneumonia: a case report. J Reprod Med 1988;33:399--401.

Neuzil KM, Wright PF, Mitchel EF, Griffin MR. Burden of influenza illness in children with asthma and other chronic medical conditions. J Pediatr 2000;137:856--64.

Neuzil KM, Reed GW, Mitchel EF, Simonsen L, Griffin MR. Impact of influenza on acute cardiopulmonary hospitalizations in pregnant women. Am J of Epidemiol 1998;148(11):1094-102.

Shahab SZ, Glezen WP. Influenza virus. In: Gonik B, ed. Viral diseases in pregnancy. New York, NY: Springer-Verlag, 1994:215--23.